K080899

AUG - 7 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Device Name

Arctic Blast Intravenous Fluid Chiller

Manufacturer Name , Address and Contact Information

Medivance, Inc.
1172 Century Drive, Suite 240
Louisville, CO 80027

Contact: Lynne Aronson, Director RA/QA
Phone: 303-926-1917
Fax: 303-926-1924

Common, Classification & Proprietary Names

Common Name:	thermal regulating system
Classification Name:	system, hypothermia, intravenous, cooling
Proprietary Name:	Arctic Blast Intravenous (IV) Fluid Chiller

Device Classification

Classification:	Class II
Classification Panel:	Cardiovascular
Classification Regulation:	870.5900
Product Code:	NCX

Indications for Use

The Arctic Blast® Intravenous Fluid Chiller is intended to cool sterile solutions during intravenous administration where clinically indicated for reduction of patient temperature.

Device Description

The Arctic Blast Intravenous Fluid Chiller is composed of two main components: a heat exchanger assembly and an adsorption cooling module.

The sterile fluid path is incorporated in the heat exchange assembly, which consists of the heat exchanger, a spike with vented drip chamber at the heat exchanger inlet, and a spike receptacle at the heat exchanger outlet. Prior to activation, the heat exchanger assembly inlet (spike) is connected to a liter bag of sterile fluid, and the outlet (spike port) is connected to a standard commercially-available intravenous infusion set.

The heat exchanger assembly is constructed of materials and components which are commonly used in the manufacture of commercially-available intravenous infusion sets.

The cooling module provides the cooling capability of the device via an adsorption process. The cooling module does not require an external power source. The cooling process is activated by pressing a button on the module. The cooling module is fully sealed and does not come into direct contact with the sterile fluid path.

Predicate Devices

Device Name	*Manufacturer*
▪ IV Fluid Cooler / Warmer	Alsius
▪ System 1025 Fast Flow Blood and Fluid Warmer	Level 1
▪ Celsius Control System	InnerCool
▪ Thermosuit	Life Recovery Systems

Substantial Equivalence

The Arctic Blast Intravenous Fluid Chiller was shown to be substantially equivalent in intended use, design, technological characteristics, materials and system features and functions to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2008

Medivance, Inc.
% Ms. Lynne Aronson
Director, RA/QA
1172 Century Drive, Suite 240
Louisville, Colorado 80027

Re: K080899
Trade/Device Name: Arctic Blast Intravenous Fluid Chiller
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: II
Product Code: NCX
Dated: July 10, 2008
Received: July 15, 2008

Dear Ms. Aronson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE (FDA Form)

510(k): K080899

Device: Arctic Blast Intravenous Fluid Chiller

Indications for Use:

The Arctic Blast® Intravenous Fluid Chiller is intended to cool sterile solutions during intravenous administration where clinically indicated for reduction of patient temperature.

Prescription Use__X__ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080899

(Optional Format 1-2-96)